Statistical and Analytical Plan:

All study practices and statistical methods are based on the International Conference on Harmonization (IHC) document “Statistical Principles for Clinical Trials.”

Data will be summarized by treatment group. Baseline characteristics, and safety outputs total overall columns will be included to summarize all subjects.

For all baseline, demographic, safety and efficacy outputs data will be summarized by treatment group.

In summary tables of continuous variables, the minimum and maximum statistics, the arithmetic mean and median, the 95% confidence interval, standard deviation, and standard error will be presented will to the same number of decimal places as the original data.
In summary tables of categorical variables, counts and percentages will be used. The denominator for each percentage will be the number of subjects within the population treatment group unless otherwise specified.

All hypothesis testing will be carried out at the 5% (2-sided) significance level unless otherwise specified.

P-values will be rounded to three decimal places. P-values less than 0.001 will be reported as <0.001 in tables.

At the conclusion of the trial, the raw data shall be analyzed by a blinded statistician of Mack Biotech, Corp. and then create a report with the clinical trial outcome.